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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,136	10/12/2000	John F. Engelhardt	875.032US1	7933

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/689,136

Applicant(s)

ENGELHARDT ET AL.

Examiner

Daniel M Sullivan

Art Unit

1636

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12,29-84 and 86-89 is/are pending in the application.
- 4a) Of the above claim(s) 37-82 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 87 is/are allowed.
- 6) ☒ Claim(s) 1-12,29-36,83,84,86,88 and 89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 20 October 2004 and 22 November 2004 have been entered.

Claims 37-82 had been withdrawn from consideration and claims 1-12, 29-36, 83, 84, 86 and 87 were considered in the Final Office Action mailed 18 June 2004. Claims 1 and 87 were amended and claims 88 and 89 were added in the 20 October Paper. Claims 88 and 89 were amended in the 22 November Paper. Claims 1-12, 29-84 and 86-89 are pending and claims 1-12, 29-36, 83, 84 and 86-89 are under consideration.

Information Disclosure Statement

The "COMMUNICATION CONCERNING RELATED APPLICATION(S)" filed 22 November 2004 has been considered.

Response to Amendment

Claim Rejections - 35 USC § 112

Claims 1-12, 29-36 and 83, 84 and 86 stand rejected and claim 88 is newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way

Art Unit: 1636

as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims were previously rejected on the grounds that the claims, as amended, encompass methods that do not comprise the step of “contacting the mammalian cell with an agent”. The Office Action asserts that there is no support in the originally filed specification and claims for a method that does not comprise the step of contacting a cell with a test agent.

Although it was indicated in the Advisory Action mailed 3 November 2004 that the proposed amendment of claim 1 to recite “identifying an agent contacted with a mammalian cell” would overcome this rejection, upon reconsideration, it is clear that the scope of the present claim is not supported in the originally filed application. Specifically, the claims do not comprise a step wherein the cell is also contacted with an adeno-associated virus, which step was comprised in all of the methods described in the originally filed specification. Although the claim recites that the agent contacted with the cell has the property of enhancing adeno-associated virus transduction of the mammalian cell, this limitation is property of the agent and not a process step. Therefore, the method comprising only the step of identifying an agent contacted with a mammalian cell is broader in scope than the methods contemplated in the originally filed specification and claims and, therefore, constitutes new matter.

Rejection of claims 1-12, 29-36 and 83, 84 and 86 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

Art Unit: 1636

Claim Rejections - 35 USC § 102

Rejection of claims 1, 4, 5, 10, 12 and 87 under 35 U.S.C. 102(b) as being anticipated by Ferrari *et al.* (1996) *J. Virol.* 70:3227-3234 is withdrawn in view of the amendment of claims 1 and 87 such that the agent enhances adeno-associated virus transport to the nucleus. The skilled artisan would not expect that the method of Ferrari *et al.* would identify an agent that enhances adeno-associated virus transport to the nucleus and the art of record provides no teaching or motivation to modify the method of Ferrari *et al.* to identify agents that enhance adeno-associated virus transport to the nucleus.

*New Grounds*Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 88 and 89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **New Matter** rejection.

The MPEP states, “[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” (MPEP § 2163.06). The MPEP further states,

Art Unit: 1636

“[w]henever the issue arises, the fundamental factual inquire is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application” (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

The claims are directed to a method comprising the step of identifying an agent that enhances “internalized” adeno-associated virus transport to the nucleus of the mammalian cell. Applicant provides no statement as to where this process step is supported by the originally filed disclosure. The claimed method purports to identify enhancement of adeno-associated virus transport to the nucleus, wherein the identification is limited to “internalized adeno-associated virus”. No such limitation is explicitly recited in the original disclosure and, upon considering the disclosure as a whole, the examiner can find no implied support for a method wherein transport of only internalized adeno-associated virus is measured. Although Examples 3 and 5 teach methods of assessing trafficking of AAV to the nucleus, the methods appear to assess trafficking of all virus bound to the plasma membrane. That is, the method measures trafficking of all cell associated AAV and not just internalized AAV. Therefore, the added limitation constitutes new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-12, 29-36 and 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Nair *et al.* (1998) US Patent No. 5,831,068.

Independent claim 1 is directed to a method comprising a single step: “identifying an agent contacted with a mammalian cell”. The remaining limitations are recited as properties of the agent contacted with the cell, which properties, according to the broadest reasonable interpretation of the claim, need not be determined in the method. Likewise, the method of independent claim 88 does not comprise a step wherein the properties of the agent recited in the claim are determined. Instead, according to the broadest reasonable interpretation of the claim, the method only comprises identifying, by any means, an agent contacted with a mammalian cell which agent has the property of enhancing adeno-associated virus transport to the nucleus. Thus, anticipation of the claimed method requires only that a cell be contacted with an agent having the properties recited and the agent be identified.

Nair *et al.* teaches a method wherein mammalian cells are contacted with an agent, one of which is identified as the proteasome inhibitor LLnL (see especially the final paragraph in column 1 and column 2, lines 30-33). The instant application teaches that LLnL is an agent that enhances adeno-associated virus transduction of the mammalian cell after viral binding to the cell

Art Unit: 1636

membrane and before second strand synthesis which yields an expressible form of the viral genome, wherein the agent enhances adeno-associated virus transport to the nucleus. Thus, the properties recited in claims 1 and 88 are inherent to the compound and the methods are anticipated by the contacting and identifying steps in the method of Nair *et al.*

Nair *et al.* further teaches that the method can be practiced using a human or murine cell according to claim 4 and each of the properties recited in claims 5-12 and 29-36 are inherent to the compound contacted and identified in the method of Nair *et al.* Thus, each of the limitations of the instant claims is anticipated by Nair *et al.* and the claims are properly rejected under 35 USC §102(b).

Allowable Subject Matter

Claim 87 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779.

The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'D. Sullivan', with a long horizontal line extending to the right.

Daniel M. Sullivan, Ph.D.
Examiner
Art Unit 1636